Instructions for Use

BW 685 / BW 685 S
Blood and Infusion Warmer

CE
0123

DE - Edition 02 / 2007

IMPORTANT:

These instructions are an essential part of the device. They must therefore be kept in a suitable place near the device and should accompany the device if it is transferred to other users.
For proper and safe use of this device it is essential that the following warnings and safety instructions, as well as the instructions for use are read and carefully observed by all users before first using the device.
It is the responsibility of those using the device to fully acquaint themselves with its proper use and operation.
If a malfunction is suspected, the device is to be taken out of service immediately and suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

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1 WARNINGS AND SAFETY INSTRUCTIONS

- In the event of any suspected malfunction while in operation, the device should be immediately removed from service and not used for infusions or transfusions until appropriate investigations have demonstrated that there has been no impairment.
- If the high temperature alarm is triggered the supply of liquid to the patient must be immediately stopped by disconnecting the connection tube to the patient. The medium being used in the device must no longer be administered to the patient.
- The device may only be fastened to infusion stands, tripods or equipment rails which are suitable due to their stability and load capacity.
- Only sterile consumables prescribed by BIEGLER may be used in conjunction with the BW 685 / BW 685 S.
- The device must only be used in areas in which the electrical installations are in accordance with the standards and regulations in force.
- Safe disconnection from the mains power supply can only be achieved by unplugging the mains plug.
- The device may not be used in rooms subject to explosion hazard.
- Repairs and modifications to the device may only be carried out by persons or service centres authorised by BIEGLER.
- The device must not be immersed in liquids or sterilised with steam or by thermochemical methods.
- All extraneous influences, such as electromagnetic waves or high temperatures are to be kept to a minimum.
- The system may malfunction due to the effect of strong electromagnetic fields (e.g. by HF therapy or surgical devices). The warmer works perfectly within the limit values of the Standard EN 60601-1-2. The system can be affected by limit values that do not comply with the Standard EN 60601-1-2.
- Avoid exerting force on the device or its accessories.
- If the device is dropped, damaged by force or if it shows a function deviating from the instructions for use, stop using the device immediately and return it to the service centre.
- The periodic technical safety inspections must be carried out (see section: “Periodic inspections”)

Supplementary safety instructions for the accessory tube warmer Biegler Tubeflow BW 685 S:

- The Biegler Tubeflow may only be clamped to the Biegler blood warmer BW 685 S with the fixing clamp according to the diagram in the chapter "Initial operation".
- Do not kink, cover, warm or cool the Biegler Tubeflow. Do not cover the Tubeflow with cloths or dressing material. Do not lead under blankets, warm air blankets, etc. Do not expose to direct sunlight or heat radiation. Lead the Tubeflow through the air unencumbered. Do not lead into or through incubators. Overwarming of the warmed liquid or burns to the patient cannot to be excluded in the case of non-compliance.
- Do not shorten or damage the Biegler Tubeflow.

The BW 685 / BW 685 S may not be used if:

- the housing is damaged or one of the front film layers becomes detached.
- the device has been exposed to a hard physical shock (e.g. dropped, hit or shaken)
- the device has been immersed in water
- the device has triggered a high temperature alarm that was not caused by external factors.
- the mains power cord or plug is damaged
- the device has given somebody an electric shock
- the fixing clamps are damaged and no longer assure safe clamping to the infusion stand.

Should a malfunction be evident, suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

2 DESCRIPTION

2.1 GENERAL DESCRIPTION

The BIEGLER BW 685 / BW 685 S is a warmer for infusions or transfusions and operates on the basis of a continuous flow warmer, where the heat from the heat exchanger is transferred via the extension tubing to the liquid flowing within it.

The patented groove design enables several extension tubes to be used, provided that each of the tubes placed in position can be warmed sufficiently.

The design of the housing allows rapid and simple fitting to all suitable infusion stands and equipment rails. The temperature of the warmer element can be set between 37°C and 41°C in steps of 0.5°C and is clearly displayed.

The preset temperature after switching on the BW 685 / BW 685 S is 38.5°C. The alarm and self-test functions for high and low temperature that are incorporated into the device assure safe operation.

Optional: The accessory tube warmer Biegler Tubeflow is available as a warming system for transfusions and infusions between BW 685 S and the patient. The system can be used in all cases in which warming of the transfusion or infusion is necessary up to the patient.

2.2 SCOPE OF DELIVERY

Blood and infusion warmer BW 685 / BW 685 S and instructions for use

Optional accessory for BW 685 S:

Tube warmer Biegler Tubeflow Order no 12000

2.3 CONSUMABLE MATERIALS

Various consumable materials are available according to requirements.

For use with BW 685 or BW 685 S without tube warmer:

Extension set	3.5 m	Order no 35000
Extension set	4.6 m	Order no 45000
Extension set with bubble trap	4.6 m	Order no 25000

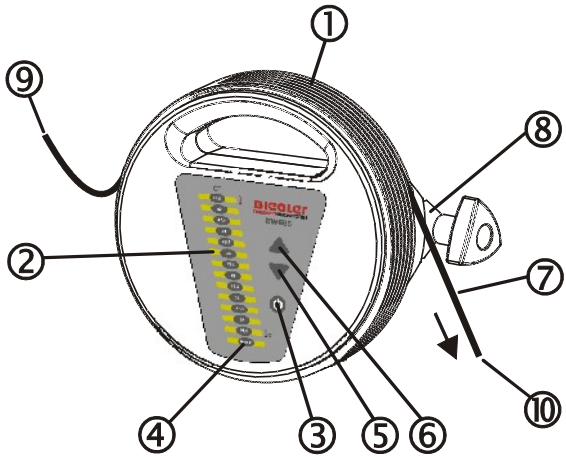
For use with BW 685 S with tube warmer:

Extension set	5.3 m	Order no 16000
Extension set with bubble trap	5.3 m	Order no 15000

3 INITIAL OPERATION

Observe the instructions for use! Users must familiarise themselves in detail with the contents of these instructions for use before putting the system into operation.

3.1 INITIAL OPERATION OF THE DEVICE



Diag. 1
1 Heat exchanger
2 Temperature scale
3 Control ON / STANDBY
4 LED STANDBY
5 Control for decreasing the temperature
6 Control for increasing the temperature
7 Extension tube
8 Fixing clamp
9 Entry of liquid
10 Exit of liquid
→ Flow direction

Fix the BIEGLER BW 685 / BW 685 S firmly to the infusion stand using the clamps at the back (Diag.1/8). Only use infusion stands, tripods or equipment rails that are sufficiently stable.

Connection of the optional tube warmer Biegler Tubeflow (to the BW 685 S): The tube warmer Biegler Tubeflow must be inserted with light pressure as indicated in diagram 3 into the intended fixture (Diag. 3/4) on the BW 685 S. Remove the dust cap from the BW 685 S and attach the connector of the Tubeflow to the female connector on the BW 685 S.

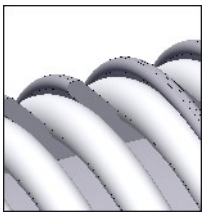
Connect the power cable to the power supply. Before connecting to the mains power supply, check the voltage specified on the device label. The device emits a short beep and the standby light (Diag.1/4) lights up.

If a temperature other than 38.5°C is desired, it can be preset in the Standby mode by using the controls ▲ and ▼ (Diag.1/5 and Diag.1/6). If an adjustment control is pressed, the visual display indicates the existing preset temperature. By repeated operation of the control ▲ or ▼, the temperature can be reset. Resetting of the temperature can only be performed in the Standby mode.

The warmer of the BW 685 / BW 685 S can be started by pressing the control ⏻ (Diag.1/3). A self-test of safety relevant device functions is carried out, which is terminated by a short acoustic signal. The BW 685 / BW 685 S attains the set target temperature within 1 minute. The actual temperature (+/- 0.5°C) is indicated on the display.

Select suitable consumable materials. See the section "Consumable materials".

Prepare infusion or transfusion. Important: The length of the tube between the BW 685 / BW 685 S and the patient must be at least 40 cm and the tube must not be stretched.



Diag. 2
Position of the tube in the groove of the heat exchanger

Beginning at the back of the heat exchanger, gently pull the extension tube and coil it in a counter-clockwise direction towards the front. It is advisable that the distance between the BW 685 / BW 685 S and the patient does not exceed much more than 80 cm.

Important: The tube must be completely inserted into the groove (Diag. 2)
The flow direction specified in diagram 1 must be complied with.

Optional accessory tube warmer Biegler Tubeflow for BW 685 S:

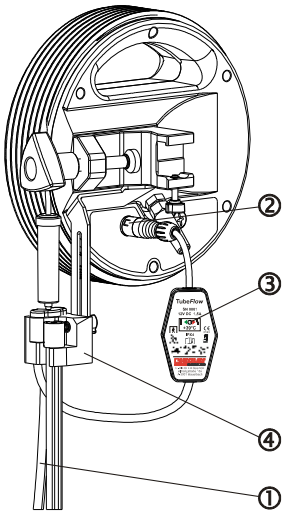
The connector as per diagram 3/2 must be connected to the BW 685 S before starting the optional tube warmer.

Insert the transfusion or infusion tube into the groove of the tube warmer. Insert the tube over the complete length of the Biegler Tubeflow.

Important: Overwarming can result, if the full length of the tube warmer is not utilised, thereby possibly harming the medium or patient, since the reference temperature sensor is located at the distal end.

Diag. 3
1 Tube warmer
2 Connector
3 Control light
(Green – Operational / red – Alarm)
Fixture

Diag.3



The Tubeflow is also activated when the BW 685 S is turned on; this is indicated by a green control light on the Tubeflow.

3.2 ALARMS

The BW 685 / BW 685 S can trigger two types of temperature alarm:

The low temperature alarm is activated when the temperature of the heat exchanger drops below 36.5°C. The audio low temperature alarm is deactivated during the first 60 seconds after switching on.

The high temperature alarm is activated when the temperature of the heat exchanger exceeds 42.0°C. In this event visual and audio alarm signals are given and the heating is switched off. To reset the device or switch off the alarm, disconnect the device from the power supply.

Important: The temperature alarm can also be set off externally e.g. by exposure to sunlight.

3.3 SHUTTING DOWN THE DEVICE

After being used for treatment, the device is shut down as follows:

Switch the device into Standby mode using control ⏻ (Diag.1/3).

Release pressure from the system by switching off possibly used pressure cuffs or infusion pumps. Empty and disconnect the system as far as possible.

Remove the consumable materials from the heat exchanger (Diag.1/1) and, if used, also from the optional tube warmer and dispose of in accordance with the applicable local regulations

Disconnect the device from the power supply and clean and disinfect according to the section "Cleaning and disinfection".

4 MAINTENANCE

The BW 685 / BW 685 S is designed as a low-maintenance device. To preserve the quality and functional safety, please comply with the following points:

- Always keep the device clean (see the section: "Cleaning and disinfection").
- The periodic technical safety inspections must be carried out (see the section "Periodic inspections")

5 CLEANING AND DISINFECTION

The BW 685 / BW 685 S and the optional tube warmer Tubeflow may only be cleaned using a soft cloth with a water-soluble, non-aggressive cleaning agent or a special cleaning agent for plastics.

For the purposes of disinfection, ready-made alcohol-based spray disinfectants can be used.

Important: Before cleaning or disinfecting, the device must always be disconnected from the mains power supply by pulling the plug.

Do not disinfect the device with steam (i.e. in autoclaves), hot air or thermochemical cleaning solutions.

6 PERIODIC INSPECTIONS

The periodic technical safety inspections (according to the local standards in force – e.g.. in Austria ÖVE/ÖNORM E 8751-1) must be carried out on the BW 685 / BW 685 S at least every 12 months by persons able to carry out such technical safety inspections based on their training, knowledge and experience gained by practical activities.

The results of the periodic inspection are to be documented, together with the date and the inspecting agency.

Important: Should a malfunction be evident, suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

CHECKING THE WARM-UP PERIOD

This is the time taken by the BW 685 / BW 685 S to heat up to 38.5°C from room temperature. The device is malfunctioning if it takes much longer than one minute.

CHECKING THE CONTROL TEMPERATURE

The control temperature is checked on the groove bed of the heat exchanger. The sensor of a suitable contact thermometer (tolerance +/- 0.15°C) is fixed to this position, e.g. by using a piece of infusion tubing. The examination is performed at a temperature setting of 38.5°C.

The measured value is read after it has stabilised. The difference must not exceed +/- 0.5°C. There is a malfunction if a difference from the control temperature of greater than +/- 0.5°C is obtained.

CHECKING THE LOW TEMPERATURE ALARM

Preheat the device to 38.5°C, then disconnect the mains plug. Hold down the control ▼ and reconnect the mains power plug. After the beep has ceased, release the control ▼. Press the switch ⏻. The device is now in an operational state where all the alarms are active, but the heating is switched off. The BW 685 / BW 685 S now slowly cools down. When the temperature drops below the 36.5°C threshold, the low temperature alarm should trigger.

For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode and the STANDBY indicator (Diag.1/4) flashes. There is a malfunction if the low temperature alarm is not triggered.

CHECKING THE HIGH TEMPERATURE ALARM

Preheat the device to 41°C and wait for the temperature to stabilise, then disconnect the mains plug. Hold down the control ▲ and reconnect the mains power plug. After the beep has ceased, release the control ▲. Press the switch ⏻. The device now slowly heats up to a target temperature of 42.5°C. Observe the temperature display carefully. The high temperature alarm should be triggered at a temperature of 42°C.
For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode and the STANDBY indicator (Diag.1/4) flashes. There is a malfunction if the high temperature alarm is not triggered.

VISUAL CHECK OF GENERAL CONDITION

The device should be checked for mechanical damage (general condition) and for the completeness of the sticker information, particularly the device label on the reverse. There is a malfunction if mechanical damage to the device is evident which could be harmful or impair the functional operation of the device.

ELECTRICAL SAFETY

All relevant electrical safety data should be checked, particularly the earth conductor resistance (Target: < 0.3 Ohm) and leakage current (Target: < 0.75 mA). There is a malfunction if there is a measured value outside the tolerances.

7 MANUFACTURER LIABILITY

The manufacturer and the supplier of the device reject all liability if:

- the device is not used in accordance with the instructions for use
- the user is not sufficiently informed about the functioning of the device on the basis of the instructions for use and the safety instructions
- repairs are not performed exclusively by the manufacturer or by persons and service centres expressly authorised by the manufacturer
- the device is used in places in which the electrical installations do not comply with the applicable national standards, or if power supply during the period of use of the device is not guaranteed
- original spare parts material are not used or the maintenance interval is not complied with.
- disposal of the device and its accessories is not carried out in accordance with the applicable local regulations.

8 WARRANTY CONDITIONS

The manufacturer guarantees that all flaws of material and workmanship which arise within 24 months from the date of purchase will be repaired free of charge.
Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier on storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer's warranty will be void if it is found that the maintenance, disinfection and inspection instructions have not been followed according to the instructions for use, the device has been damaged by force or operating error or has been used in any way contrary to the instructions for use and safety instructions. The warranty will also be void if original Biegler materials were not used as replacement parts, or measures for repair were undertaken by persons not authorised by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier shall under no circumstances assume liability for slight negligence. The compensation for lost earnings and profits is likewise excluded.

9 RETURN OF DEVICES

Devices must be carefully cleaned and disinfected before being placed in the original packaging for returning.

If the original packaging is no longer available, the product has to be suitably packaged for the method of dispatch.

10 ELECTROMAGNETIC COMPLIANCE

Table 201

Guidelines and manufacturer's declaration – electromagnetic emission		
The BW685 is intended for use in the environment specified below. The customer or the user of the BW685 should assure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions acc. to CISPR 11	Group 1	The BW685 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class B	The BW685 is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network that also supplies buildings used for domestic purposes.
Emission of harmonics acc. to IEC 61000-3-2	Class A	
Emission of harmonics acc. to IEC 61000-3-3	Complies	

Table 202

Guidelines and manufacturer's declaration – electromagnetic interference resistance

The BW685 is intended for use in the electromagnetic environment specified below. The customer or the user of the BW685 should assure that it is used in such an environment.

Interference resistance test	IEC 60601- test level	Compliance level	Electromagnetic environment - guideline
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast transient /electrical bursts acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	The mains power supply quality should be that of a typical commercial or hospital environment.
Surge voltages (surges) acc. to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV normal mode voltage ± 2 kV common mode voltage	The mains power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations of the supply voltage acc. to IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 s	The mains power supply quality should be that of a typical commercial or hospital environment. If the use of the BW685 requires continued operation during power mains interruptions, it is recommended that the BW685 be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note U_T is the AC mains voltage prior to application of the test level.

Table 204

Guidelines and manufacturer's declaration – electromagnetic interference resistance to

The BW685 is intended for use in the electromagnetic environment specified below. The customer or the user of the BW685 should assure that it is used in such an environment.

Interference resistance test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of the BW685, including cables, than the recommended protection distance calculated from the equation applicable to the frequency of the transmitter: **Recommended protection distance:**
Conducted RF disturbance variables acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$V1$ in V	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Emitted RF disturbance variables acc. to IEC 61000-4-3	3 V/m 80 kHz to 2.5 GHz	$E1$ in V/m	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ for 80 MHz to 800 MHz
			$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended protection distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from stationary transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to stationary RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BW685 is used exceeds the applicable RF compliance level as specified above, the BW685 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BW685.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 206

Recommended protection distances between portable and mobile RF communications equipment and the BW685			
The BW685 is intended for use in an electromagnetic environment in which radiated RF disturbance variables are controlled. The customer or user of the BW685 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BW685 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Protection distance according to transmitter frequency m**		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended distance can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

11 MANUFACTURER'S DECLARATION

The blood and infusion warmer BW 685 / BW 685 S is a medical product as defined by Directive 93/42/EEC.

This is documented by attaching the CE mark.
Notified Body: TÜV Product-Service, Approval Number CE0123

12 SYMBOLS

CE 0123 Certifies compliance with the Directive 93/42/EEC

Observe the instructions for use!

Do not dispose of this product as unsorted municipal waste

Control for increasing the temperature setting

Control for decreasing the temperature setting

IPX 4 Humidity Classes

Degree of protection B

Control for switching On / Standby

- for optional tube warmer Tubeflow

Operation

Malfunction

Do not cover

Do not wrap up

Do not expose to direct sunlight

Do not cut

13 OPERATING AND STORAGE CONDITIONS

Permissible environmental conditions for transport and storage:

Temperature:	10 – 40°C
Relative humidity:	30 – 75%
Air pressure:	700 – 1060 hPa

The ambient operating temperature must be in the range of 10 – 30°C. Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

14 TECHNICAL DATA

Device:	Blood and infusion warmer
Type designation:	BW 685 / BW 685 S
Voltage:	230 V / 50Hz
Power consumption:	1.5 A
Protection class:	I
Degree of protection:	B
Humidity protection:	IPX4
Fuses:	primary 2 x 1.6 AT secondary 500 mAT
Control temperature:	37°C - 41°C adjustable in 0.5°C steps
Overtemperature shutdown:	42°C / 42.5°C / 45°C±3°C
Max. system pressure:	300 mm Hg
Classification:	IIb according to Rule 9
Operational mode:	Continuous operation
Dimensions BW 685:	WxHxD 228 x 228 x 132 mm
Weight BW 685:	1.9 kg
Dimensions BW 685 S:	WxHxD 228 x 278 x 132 mm
Weight BW 685 S:	2.0 kg
Tube warmer Tubeflow for BW 685 S:	Length 1340mm

15 MANUFACTURER

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